	١	
_	T	

Sut	bstitute fo	r form 144	·9A/PTO	Con	nplete if Known
			TION DISCLOSURE	Application Number	Centinuation of 10/211,215
	(use as ma	ny sheets as necessary)	10/706, 243 Filing Date	November 12, 2003
				First Named Inventor	Solomon Steiner
				Group Art Unit	
				Examiner Name	
$\neg \tau$	1	of	5	Attorney Docket Number	PDT 103 CON (3)

			U.S. PATENT DOCUM	TENTS	
Examiner Initials*	Cite No.1	US Patent Document	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code ² (if known)			· · · · · · · · · · · · · · · · · · ·
K6		3,906,950	Cocozza	09-23-1975	
1		3,921,637	Bennie, et al.	11-25-1975	
\neg		4,272,398	Jaffe ·	06-09-1981	
	4,861,627		Mathiowitz	08-29-1989	
		5,145,684	Liversidge, et al.	09-08-1992	
		5,260,306	Boardman, et al.	11-09-1993	·
$-\Box$		5.352,461	Feldstein, et al.	10-04-1994	
-H		5,458,135	Patton, et al.	10-17-1995	
$\neg \sqcap$		5,492,112	Mecikalski, et al.	02-20-1996	•
\neg		5,577,497	Mecikalski, et al.	11-26-1996	
		5,653,961	McNally, et al.	08-05-1997	
		5,658,878	Bäckström, et al.	08-19-1997	
		5,740,794	Smith, et al.	04-21-1998	
-		5,747,445	Bäckström, et al.	05-05-1998	
166	*****	5,785,049	Smith, et al.	07-28-1998	

				F	OREIGN PATENT DOCUMENT	'S			
Examiner Initials*	No.3			Foreign Patent Docum	nent	Name of Patentes or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т*
		Office.3	Number*	Kind Code ⁶ (if known)			•		
K.G		EΡ	0 257 915		Innovata Biomed Ltd.	02-03-1988		<u> </u>	
1		GB	2 240 337		National Research Development Corporation	07-31-1991			
	1	JP	2-149545		Taisho Pharmaceutical Co.	02-12-1992		<u> </u>	
\neg	 	PCT	WO 91/04011		Riker Laboratories Inc.	04-04-1991			
		PCT	WO 92/08509		Minnesota Mining and Manufacturing Company	05-29-1992		<u> </u>	
Ko		PCT	WO 93/02712		Danbiosyst UK Limited	02-18-1993		<u> </u>	

Examine Signature	KdM/~	Date Considered	8/2005	
0.3				

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

	Substitute for form 1449A/PTO			Complete if Known			
	INI	FORMA	TION DISCLOSURE	Application Number	Continuation of 10/211,215		
	ST		ENT BY APPLICANT	10/706,243			
		(000 00 111	2.1.y 51.0515 d2 1.055552.y,	Filing Date	November 12, 2003		
				First Named Inventor	Solomon Steiner		
				Group Art Unit			
	•		•	Examiner Name			
Sheet	2	of	5	Attorney Docket Number	PDT 103 CON (3)		

			U.S. PATENT DOCUM	ENTS	
Examiner Initials*	Cite No.'	US Patent Document	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code ² (if known)	•		
16		5,874,064	Edwards, et al.	02-23-1999	
1		5,901,703	Ohki, et al.	05-11-1999	
		5,952,008	Bäckström, et al.	09-14-1999	
Ks		5,997,848	Patton, et al.	12-07-1999	
				-	

		S	OREIGN PATENT DOCUMENT	F				
ssages or Relevant	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		Name of Patentee or Applicant of Cited Document	Foreign Patent Document			Cite No.1	Examiner Initials*
			1	Kind Code ⁵ (if known)	Number ⁴	Office.		
		09-30-1993	Pharmaceutical Discovery Corporation		WO 93/18754	PCT		166
	· · · · · · · · · · · · · · · · · · ·			1				
	·							
			•					

Examine Signature	KotaM	6	Date Considered	8	/2005	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁶ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

	Substitute fo	r form 14	19A/PTO	Co	mplete if Known
			N DISCLOSURE	Application Number	Continuation of 10/211,215
STATEMENT BY APPLICANT (use as many sheets as necessary)				10/706,243	
	(400	25 1114117 0	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Filing Date	November 12, 2003
				First Named Inventor	Solomon Steiner
				Group Art Unit	
				Examiner Name	
				Attorney Docket Number	PDT 103 CON (3)

		OTHER ART NON PATENT LITERATURE DOCUMENTS	
Examiner's	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	T2
Initials*	No.1	item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s),	
		publisher, city and/or country where published	
l		BENITA, "Characterization of Drug-Loaded Poly(d, Flactide) Microspheres," J. Phann. Sci., 73: 1721-1724 (1984).	
146			
1	•	BENSCH, et el., "Absorption of intact protein molecules across the pulmonary air-tissue barrier," Science 156: 1204-1206 (1967).	
		ELLIOTT, et al., "Parenteral absorption of insulin from the lung in diabetic children," Austr. Paedietr. J. 23: 293-297 (1987).	-
		GUPTA, "Contemporary Approaches in Aerosolized Drug Delivery to the Lung," J. Controlled Release, 17(2): 127-147 (1991).	+
	<u>:</u>	HEYDER, "Alveolar deposition of inhaled particles in humans," Am. Ind. Hyg. Assoc. J. 43(11): 864-866 (1982).	+
- .		KATCHALSKI, "Synthesis of Lysine Anhydride," J. Amer. Chem. Soc., 68: 879-880 (1946).	+
		KOMADA, et al., "Intratracheal delivery of peptide and protein agents: absorption from solution and dry powder by rat lung," J. Pharm. Sci. 83(6): 863-867 (1994).	
		KOPPLE, "A Convenient Synthesis of 2,5-Piperazinediones," J. Org. Chem., 33(2): 862-864 (1968).	+
		LIM, "Microencapsulation of Living Cells and Tissues," <i>J. Phann. Sci.</i> , 70: 351-354 (1981).	
16	·-·	MATHIOWITZ, "Morphology of Polyanhydride Microsphere Delivery Systems," Scanning Microscopy, 4: 329-340 (1990).	-

Examiner's	KAMC	Date	8/2005
Signature	LOVILL	Considered	01000

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁵ Applicant to place a check mark here if English language Translation is attached.

Sheet

	PT	0/SB/08A (10-98
Approved for use th	rough 10/31/89.	CINCE 0651-0031
Patent and Trademark Officer 13	S OFPARTMEN	T OF COMMERCE

Substitute for form 1449A/PTO	Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number 10/706, 243	Continuation of 10/211,215	
tuse as many shoots as necessary,	Filing Date	November 12, 2003	
	First Named Inventor	Solomon Steiner	
	Group Art Unit		
	Examiner Name		
4 of 5	Attorney Docket Number	PDT 103 CON (3)	

		OTHER ART NON PATENT LITERATURE DOCUMENTS	T²			
Examiner's Initials*						
16		MATHIDWITZ, "Novel Microcapsules for Delivery Systems," Reactive Polymers, 6: 275-283 (1987).				
1		MATHIDWITZ, "Polyanhydride Microspheres As Drug Carriers L. Hot-Melt Microencapsulation," J. Controlled Release, 5: 13-22 (1987).				
		MATHIOWITZ, "Polyantrydride Mocrospheres as Drug Carriers. II. Microencapsulation by Solvent Removal," J. Appl. Polymer Sci., 35: 755-774 (1988).				
K6		MATHIDWITZ, "Polyanydride Microspheres. IV. Morphology and Characterization of Systems Made by Spray Drying," J. Appl. Polymer Sci., 45: 125-134 (1992).				
,		MOREN, <u>Aerosols in Medicine</u> , (2nd ed.), Elsevier, pp. 321-350.				
K6		OKUMURA, et al., "Intratracheal delivery of insulin. Absorption from solution and serosol by rat lung," Int. J. Pharmaceuticals 88: 63-73 (1992).				
1		PATTON & PLATZ, "Routes of Delivery: Case Studies. Pulmonary delivery of peptides and proteins for systemic action," Adv. Drug. Del. Rev. 8: 179-196 (1992).				
		SALIB, "Utilization of Sodium Alginate in Drug Microencapsulation," Pharazeutische Industrie, 40(11a): 1230-1234 (1978).	_			
	 -	SAWHNEY, "Bioerodible Hydrogels Based on Photopolymerized Polylethylene glycol)-co-polyla-hydroxy acid) Diacrylate Macromers," Macromolecules, 26: 581-587 (1993).				
KG		WIGLEY, et al., "Insulin across respiratory mucosae by aerosol delivery," Diabetes 20(8): 552-556 (1971).				

			 	.	
Examiner's	1/ JM	1	Date	8	2005
Signature	KATALI		 Considered	0	200)

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number 2 See attached Kinds of U.S. Patent Documents. 2 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). • For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. • Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. • Applicant to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO			9A/PTO	Complete if Known		
			N DISCLOSURE BY APPLICANT	Application Number	Continuation of 10/211,215	
			neets as necessary)	10/706,243		
				Filing Date	November 12, 2003	
				First Named Inventor	Solomon Steiner	
				Group Art Unit		
				Examiner Name		
	5	of	5	Attorney Docket Number	PDT 103 CON (3)	

		OTHER ART NON PATENT LITERATURE DOCUMENTS	T ³			
Examiner's Initials*	Cite No.1	item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published				
KG	WITCHERT, "Low Molecular Weight PLA: A Suitable Polymer for Pulmonary Administered Microparticles," J. Microencapsulation, 10(2): 195-207 (1993).					
K 6						
		·				
,						

Examiner's Signature	16 Am	Mc_	Date Considered	81	2005	
<u> </u>	<u> </u>					

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.